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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

FERKO, KATHRYN P

ART UNIT

PAPER NUMBER

3743

DATE MAILED: 09/11/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/732,835

Applicant(s)

ROE ET AL.

Examiner

Kathryn Odland

Art Unit

3743

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 December 2000.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-11, 13-18 and 46-66 is/are pending in the application.
- 4a) Of the above claim(s) 12 and 19-45 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-11, 13-18 and 46-66 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 05 March 2001 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4, 5.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Drawings

1. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they do not include the following reference sign(s) mentioned in the description: elements 166, 264. A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

Specification

2. The disclosure is objected to because of the following informalities: page 12 makes reference to a co-pending application. The serial number needs to be filled in the blank that was provided. Also, on page 32, for example, element 20 is labeled as sheath in line 1 and distal end in line 5. For clarity, each reference numerals should only have one label.

Appropriate correction is required.

3. The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.

Claim Objections

4. Claim 62 is objected to because of the following informalities: there appears to be a typographical error in line 2 with the phrase, "[I]ntroducing one or instruments through...." Appropriate correction is required.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

6. Claim 59 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 59 recites, "wherein the actuator is configured for retracting the positioning elements into the tubular member when the closure element is deployed for the housing." It is not understood what is meant by the phrase, "[o]r the housing."

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 1-9, 11, and 16 are rejected under 35 U.S.C. 102(b) as being anticipated by Green et al. in EP 0774237.

Green et al. disclose an apparatus for delivering a closure element into a passage communicating with an opening into a body lumen having:

- An elongate member (20/30) having proximal and distal ends, as recited in column 6, lines 45-60 and seen in figures 2 and 3
- An annular clip (26) carried by the elongate member for closing the opening, as recited in column 6, lines 50-55 and seen in figures 2 and 3

- A locator member (60) coupled to the elongate member, where the locator member has a distal portion extending distally beyond the distal end of the elongate member, as seen in figure 15
- One or more positioning elements (62b and 64b) on the distal portion of the locator member, where the positioning elements are selectively expandable between a substantially axial compressed configuration and a substantially transverse expanded configuration, as seen in figures 12 and 15
- Positioning elements that are splines (62b and 64b) configured for expanding substantially transversely with respect to a longitudinal axis of the elongate member, as seen in figure 15
- One or more positioning elements (62b and 64b) that are a plurality of substantially flexible splines, as recited in column 8
- One or more positioning elements (62b and 64b) that are a pair of splines disposed opposite one another about the distal portion, as seen in figure 15
- Each spline that have a first fixed end (62a and 64a) and a second movable end (at the junction of 63 and 65), the second end being axially movable towards the first to cause the first end to cause an intermediate region (at 62b and 64b) of the spline to expand transversely outward, thereby defining the substantially transverse expanded configuration, (when moving from the compressed to relaxed state the region of 63 and 65 will move toward the 62a and 64a region in order for 62b and 64b to expand outwardly

- A locator member (60) that has a control member (68) having a distal end coupled to the second end of each spline, the control member being movable axially with respect to the elongate member to selectively expand the splines between the collapsed configuration and the expanded configuration, as seen in figure 8
- An actuator (75) coupled to the locator member (60), the actuator configured for selectively expanding the positioning element from the collapsed configuration to the expanded configuration, as recited in column 9
- An actuator (75) that is configured for selectively expanding the positioning elements to a desired angle with respect to a longitudinal axis of the locator member (wherein it can be selected from the closed position to the open position and the angle of the open position is desired)
- A housing (34) slidably (slidable with respect to the sliding of the assembly via 42) disposed on an exterior of the elongate member (30), the housing configured for releasably holding the clip, where the housing is actuatable for advancing the clip distally toward the distal end of the elongate member for deploying the clip, as recited in column 7
- A elongate member (20/30) that has an introducer sheath (100) including a lumen therethrough, and wherein the locator member is removably insertable into the lumen, the distal portion of the locator member having a size for insertion through the lumen when the positioning members are in the collapsed configuration, as recited in column 9

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. Claims 10, 13-15, 17-18, and 46-66 are rejected under 35 U.S.C. 103(a) as being unpatentable over Green et al. in EP 774237 in view of Hathaway et al. in US Patent No 5,304,184.

Green et al. also disclose an apparatus for delivering a closure element into a passage communicating with an opening into a body lumen having:

- An elongate member (20/30) having proximal and distal ends
- A locator member (60) having a distal portion extending distally beyond the distal end of the elongate member
- One or more positioning elements (62b, 64b) on the distal portion of the locator member that are selectively expandable between a substantially axially collapsed configuration and a substantially transverse expanded configuration
- Positioning elements (62b, 64b) that each have a spline with a first fixed end and a second movable end where the second end is axially movable towards the first end to cause an intermediate region of the spline to expand transversely outward, thereby defining the substantially transverse configuration

- An actuator (75) coupled to the locator member (60) configured for selectively expanding the positioning elements from the collapsed configuration to the expanded configuration
- An elongate member (20/30) that has an introducer sheath (100) and where the locator member is insertable into a lumen of the sheath, as recited in column 9
- An apparatus for delivering a closure element into a passage communicating with an opening in a body lumen having:
- A locator that is insertable into a tubular member where the locator member and the tubular member have cooperating detents for substantially securing the locator member with respect to the tubular member
- An actuator that is further configured for automatically collapsing the positioning elements to the collapsed configuration upon advancement of the housing
- A locator member that has a substantially rigid sleeve extending beyond the distal end of the sheath, the positioning elements deployable axially from within the sleeve

However, Green et al. do not explicitly recite:

- An actuator that is configured for *selectively expanding the positioning elements to one of a plurality of expanded diameters*
- Opposing positioning elements that may be expanded to *complementary angles* with respect to the longitudinal axis
- *An actuator coupled to the housing* configured for advancing the housing distally to deploy the clip therefrom

- A spring mechanism for biasing the housing distally upon activation of the actuator
- A sheath and locator member that include *cooperating detents* for substantially securing the locator member axially with respect to the sheath when the locator is fully inserted into the sheath
- An elongate member and locator member that include *cooperating detents* for substantially securing the locator member axially with respect to the elongate member
- An actuator that is configured for automatically collapsing the positioning elements to the collapsed configuration *upon advancement of the housing*

On the other hand, Hathaway teach an actuator that is configured for *selectively expanding the positioning elements to one of a plurality of expanded diameters*, see figure 18 and a spring mechanism, as recited in column 10. Therefore, it would be obvious to one with ordinary skill in the art to modify the invention of Green et al. to include actuator that is configured for selectively expanding the positioning elements to one of a plurality of expanded diameters, for the purpose of controlling the expansion. Although, not explicitly recited, it would also be obvious to one with ordinary skill to have opposing positioning elements that may be expanded to complementary angles with respect to the longitudinal axis for the purpose of proper function at vessel entrances at different angles. Further, it would be obvious to include spring mechanism for biasing the housing distally upon activation of the actuator where the actuator is coupled to the housing configured for advancing the housing distally to deploy the clip therefrom. To

have the housing stationary and a push rod deploy the clip or an actuator that is coupled to the housing configured for advancing the housing distally to deploy the clip therefrom can be considered both within the scope of the invention and obvious variants to one with ordinary skill in the art. Moreover, cooperating detents would also be obvious to one with ordinary skill in the art and within the scope of the invention for providing proper alignment

Moreover, the modifications to Green et al. would provide the method for delivering a closure element into a passage communicating with an opening in a wall of a body lumen via:

- Positioning an elongate member (20, 30) through a patient's skin towards the body lumen via the passage, the elongate member includes a lumen extending between its proximal and distal ends
- Providing a locator (60) having a distal portion extending beyond the distal end of the elongate member and into the body lumen
- Expanding one or more positioning elements on the distal portion of the locator from a collapsed configuration to an expanded configuration
- Withdrawing the elongate member and locator partially until the positioning elements in their expanded configuration contact the wall of the body lumen, thereby providing a tactile indication of a location of the distal end of the elongate member
- Delivering a clip via the elongate member into the passage

- Withdrawing the elongate member and locator from the body lumen opening leaving the clip to substantially close the opening
- An elongate member that has an introducer sheath and one or [more] instruments through the lumen of the sheath into the body lumen
- Performing a diagnostic or therapeutic procedure using the one or more instruments at a location accessed via the body lumen
- A body lumen that is a blood vessel and where the procedure is at least one of angioplasty, atherectomy, stent delivery, delivery of a therapeutic agent, and tissue ablation
- An elongate member that is a tubular body where the locator is inserted into the tubular body and is axially fixed with respect to the tubular body when the locator is fully inserted into the tubular body
- Advancing a housing distally along an exterior of the elongate member where the housing is releasable holding the clip when delivering the clip

Double Patenting

11. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

12. Claims 1-11, 13-18, and 46-66 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-36 of U.S. Patent No. 6,277,140. ✓ Although the conflicting claims are not identical, they are not patentably distinct from each other because they disclose the same subject matter, perhaps slightly more broad in some aspects while slightly more narrow in others.

13. Claims 60-66 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 32-44 of copending Application No. 10/081,726. ✓ Although the conflicting claims are not identical, they are not patentably distinct from each other because they disclose the same subject matter, perhaps slightly more broad in some aspects while slightly more narrow in others.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

14. Claims 1-11, 13-18, and 46-66 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 12-21, 32, and 41-44 of copending Application No. 10/081,725. Although the conflicting claims are not identical, they are not patentably distinct from each other because they disclose the same subject matter, perhaps slightly more broad in some aspects while slightly more narrow in others.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

15. Claims 46-66 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 11, 40, and 47 of copending Application No. 09/732,835. Although the conflicting claims are not identical, they are not patentably distinct from each other because they disclose the same subject matter, perhaps slightly more broad in some aspects while slightly more narrow in others.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

16. Claims 1-11, 13-18, and 46-66 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-42 of copending Application No. 10/081,723. Although the conflicting claims are not identical, they are not patentably distinct from each other because they disclose the same subject matter, perhaps slightly more broad in some aspects while slightly more narrow in others.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

17. Claims 1-11, 13-18, and 46-66 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-33 of copending Application No. 10/081,717. Although the conflicting claims are not identical, they are not patentably distinct from each other because they disclose

the same subject matter, perhaps slightly more broad in some aspects while slightly more narrow in others.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

18. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure are as follows: US 2003/0125766; US 2002/0077657; US 2002/0026215; US Patent No. 6,547,806; US Patent No. 6,409,739; and US Patent No. 6,334,865.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kathryn Odland whose telephone number is (703) 306-3454. The examiner can normally be reached on M-F (7:30-5:00) First Friday Off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Henry A Bennett can be reached on (703) 308-0101. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1113.

KO


Henry Bennett
Supervisory Patent Examiner
Group 3700